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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,145	07/31/2003	Garland L. Segner	EV31008US	1829

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/632,145	Applicant(s) SEGNER ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 10, 11, 16, 22, 23, 26-29, 31, 32, 37, 43-47 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-9, 12-15, 17-20, 24, 25, 30, 33-36, 38-41 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/632,145</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species I in the reply filed on 10/13/2005 is acknowledged. The traversal is on the ground(s) that Species I: embodiment disclosed in Figure 1 contains Figures 1 A-F because there is no Figure 1 and Figure 1G and Figures 1 H-J are listed as other species. The examiner notes that Species I does include Figures 1 A-F and applicant correctly interpreted and replied because Figures 1 A-F involve substantially similar structures/ geometries of the distal tapered region of the guidewire and not the means of attaching the distal region or substantially different embodiments of the core and/or tie layer structure/ geometry relationships. Moreover, applicant traverses the ground that claims 1, 2, 7-9, 12-15, 17-21, 24, 25, 30, 33-36, 38-42, and 48 read on the elected species and the examiner concurs.
2. Claims 3-6, 10, 11, 16, 22, 23, 26-29, 31, 32, 37, 43-47 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/13/2005.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on 07/31/2003, 11/17/2004, 01/20/2005, 04/28/2005 and 05/25/2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements.

***Specification***

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

a. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

b. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The abstract of the disclosure is objected to because of legalese. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1, 2, 7-9, 12-14, 17-19, 24, 25, 30, 33-35, 38-40, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Palermo et al (5749837). For claims 1, 24, and 48 Palermo discloses a elongate flexible guidewire 100 having proximal and distal regions with associated ends wherein said distal region and associated end includes a distally tapered portion (column 4 line 3). Palermo shows said guidewire 100 further comprises a plurality of wire strands 112,132 helically wrapped parallel to one another and disposed on tapered distal region 104 of the core. Furthermore, Palermo discloses a polymer tie layer 204 disposed along the wire strands (column 4 line 13) and a lubricious polymer layer 206 disposed on the tie layer (column 4 line 11) wherein said tie layer provides the only form of attachment of wire strands 112 to core 110 (column 6 line 33).

9. For claims 2 and 25, Palermo discloses the polymer tie layer 204 to be disposed over the entire length of the guidewire (column 5 line 23). For claim 7, as mentioned above, the polymer tie layer provides the only form of attachment of wire strands to core (column 6 line 33). For claim 8, Palermo shows the plurality of wire strands 112,132 attached to core 110 by solder or adhesives (column 4 line 6 and column 5 line 40). For claims 9 and 30, Palermo shows in Figure 5A the guidewire core extending to the distal end of the guidewire. For claims 12, 13, 33, and 34, Palermo discloses the length of the guidewire is typically about 50 to 300 cm (column 4 line 6). For claims 14 and 35, Palermo discloses the outer diameter of the guidewire is typically about 0.010 to 0.025 inches (column 5 line 4). For claims 17 and 38, Palermo discloses the length of the distal wire strands to be about 25 to 35 cm (column 7 line 15). For claims 18 and 39,

Palermo discloses the outer diameter of the distal tip to be about 0.005 to 0.020 inches (column 6 line 14). For claims 19 and 40, Palermo discloses the length of the distal region of the guidewire core to be about 20 to 50 cm (column 6 line 12).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 15, 20, 36, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo in view of Fleischhacker et al (5165421). For claims 15 and 36, Palermo discloses the claimed guidewire except for the guidewire comprising 3 to 24 wire strands. Fleischhacker teaches the use of a plurality of multifilar helically wound coil wires to comprise the guidewire (column 3 line 37) as seen in Figure 2. It would have been obvious to one having ordinary skill in the art at the time the invention was

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made to modify the guidewire as taught by Palermo, with Fleischhacker for the purpose of structuring the guidewire in such a manner to control flexibility and torqueability by increasing or decreasing the number of wire strands.

13. For claims 20 and 41, Palermo discloses the claimed guidewire except for the plurality of helically disposed wire strands forming a tubular structure and wherein a portion of the distally tapered region is disposed within the tubular structure.

Fleischhacker teaches the use of a plurality of multifilar helically wound coil wires to comprise a tubular structure and disposing within the distally tapered guidewire region (column 6 line 58) as seen in Figures 9 and 10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Palermo, with Fleischhacker for the purpose of structuring the guidewire in such a manner to control the flexibility of the distal region.

14. With respect to claims 21 and 42, we agree with the board that the limitation of the "angle between wire strands and the central longitudinal axis being 10 to 45 degrees," which is physically limited to 1 to 90 degrees, presents no novel or unexpected result over the helically coiled wire strands used in the Palermo and Fleischhacker. Use of such a means of coil wrapping in lieu of those used in the references solves no stated problem and would be an obvious matter of design choice within the skill of the art. In re Launder, 42 CCPA 886, 222 F.2d 371, 105 USPQ 446 (1955); Flour City Architectural Metals v. Alpana Aluminum Products, Inc., 454 F. 2d 98, 172 USPQ 341 (8th Cir. 1972); National Connector Corp. v. Malco Manufacturing Co.,

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392 F.2d 766. 157 USPQ 401 (8th Cir.) cert. denied, 393 U.S. 923, 159 USPQ 799 (1968).

**Conclusion**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

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